Opportunities to Achieve Substantial Savings For Patients Through Greater Generic Pharmaceutical Utilization

Testimony of the Generic Pharmaceutical Association (GPhA) Before the Subcommittee on Health, House Committee of Energy and Commerce

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On Behalf of the
Generic Pharmaceutical Association (GPhA)

Mr. Chairman and Members of the Committee. I'm Kathleen Jaeger, President and CEO of the Generic Pharmaceutical Association. Today I am pleased to speak on behalf of nearly 130 member companies that manufacture and distribute generic pharmaceutical products, including bulk active pharmaceutical chemicals.

We appreciate the opportunity to discuss current generic pharmaceutical utilization and the opportunities available to tap a substantial reservoir of additional savings for consumers, as well as for State- and Federally-funded programs. Because your committee has such broad jurisdiction over our nation's health care programs, including private insurers, Medicaid, and much of the Medicare program, we well recognize your keen interest in and knowledge about the impact of growing pharmaceutical cost on all purchasers of health care. GPHA's recommendations for achieving substantial savings can be accomplished by adopting initiatives in two broad categories:

1) Adopting initiatives that would increase generic utilization and produce substantial savings; and
2) Preventing initiatives that would erect new barriers to generic competition and thus increase overall cost.

First, I would like to provide a brief overview of the safety and sameness of generic drugs as well as to discuss recent pharmaceutical cost trends. For more than two decades, FDA-approved generic medicines have been providing consumers with the same medicines, and offering the same clinical results as their brand name counterparts at a substantial savings for consumers.

The rigorous FDA-approval process for generics ensures that our products have the same active ingredients, are taken in the same way, provide the same dose, and produce the same clinical results. Repeatedly since the founding of our industry, the FDA has assured the general public, doctors and healthcare providers that the only difference between a generic drug and its brand name counterpart is the cost. Our products have been used to fill over tens of billion prescriptions, a track record for safety and sameness that stands on its own.

Generic pharmaceuticals represent more than 53 percent of all prescriptions dispensed in the United States, but they account for only 12 percent of all dollars spent on prescription drugs. According to various studies, generics can be as much as 80 percent less than brands. And, according to the National Association of Chain Drug Stores, last year the average retail price for a brand drug was $96.01 while the average retail price of a generic was $28.74, a savings of nearly 70 percent per prescription.

It is important to note that while current generic utilization saves America tens of billions of dollars each year on the cost of medicines, increasing utilization will introduce even more dramatic savings.

Recently, AARP released its annual Rx Watchdog Report, which tracks prices that drug manufacturers charged wholesalers during the past year for about 200 prescription drugs popular with older Americans. The brand pharmaceutical price hikes were the largest annual jump since AARP began sponsoring the study five years ago.

According to the report, the 7.1 percent hike continues a trend of increasing brand drug prices, despite the fact that inflation in 2004 was 2.7 percent. The report also noted that in contrast, the price for 75 popular generic drugs hardly budged in 2004, rising 0.5 percent, 2.2 percent below the rate of inflation.

The value of generic medicines as the prescription for relief from high drug costs was further confirmed in a December 2004 study released by the Department of Health and Human Services. While we believe the number to be much higher, the HHS study found that in the

United States, "if consumers were to buy generic products whenever possible ... we estimate savings to be approximately $17 billion."

Clearly, greater use of generic pharmaceuticals could help arrest the escalation of drug spending at both the federal and state levels, and for individual consumers as well. Promoting the increased utilization of generic drugs is therefore, quite simply, good and affordable medicine for everyone.

Yet, as I indicated previously, there remain a number of opportunities and threats to substantially enhancing the savings potential that generic pharmaceuticals provide.

I. INITIATIVES THAT WOULD INCREASE GENERIC UTILIZATION AND PRODUCE SUBSTANTIAL SAVINGS

Adopting or encouraging the use of practices that immediately increase the use of FDA-approved generic pharmaceuticals in place of expensive brand name drugs is imperative. In fact, a one percent increase in generic utilization yields almost 4 billion dollars in savings!![1]

One critical step that deserves immediate consideration by Congress is the adequate funding and oversight of FDA's generic approval division, the Office of Generic Drugs (OGD). Lack of sufficient oversight and accountability at the Commissioner and Center levels, allows generic applications to endure needlessly protracted legal and scientific consults – delaying generic approvals for several months to several years. Also, allocations for OGD have remained flat for the past couple of years, and the result of this constraint on resources is clear.

Today, when consumers need FDA-approved generic medicines more than ever before, more than 700 applications languish due to lack of resources at OGD. Cooperative efforts between our industry and the staff of the Office of Generic Drugs have resulted in a streamlining of the approval process and better generic pharmaceutical applications. Yet, due to the lack of sufficient agency

[1] 2005 IMS Health: National Sales Perspective (2004 Data Analysis) & IMS Health NPA

accountability and OGD resource constraints, approvals significantly lag behind the increasingly strong applications of our member companies. Moreover, this problem will only worsen over the next few years as more generic drug applications are submitted for equivalents of blockbuster brand products that come off patent: $27 billion in 2007, $29 billion in 2008, $21 billion in 2009 and $44 billion in 2010. [2]

Congress can, and should, require accountability and increase funding to support more timely approvals. The return on investment from more accountability and increased funding will pay significant and long-lasting dividends for all Americans – individual consumers, employers and state governments and the federal government.

GPhA believes that there are a number of additional ways to immediately and effectively increase generic utilization rates on the national and state level, for Medicaid and other federal programs, for state funded programs, and for private insurers and individual consumers who must pay out of pocket.

While not all-inclusive, GPhA has identified several initiatives that alone, or in combination, would help increase the utilization of more affordable generic medicines. Four of these proposals involve changes related to the way generic medicines are prescribed and substituted. Three of our proposals address incentives and the value of efficient cost management. One initiative focuses on the value of education.

We also want to take the opportunity of this hearing to raise a flag on several issues currently looming on the legislative and international horizon that could derail America's leadership in safe and effective affordable pharmaceutical products.

Let's look first at prescribing practices and generic substitution. The easiest, and most immediate, place to start saving on prescription medicines involves the often overlooked prescription pad, and physician prescribing practices.

[2] Bain & Company.

The format of a prescription pad varies from state to state. Yet, this format can have a profound impact on whether physicians are more or less likely to prescribe brands over generics. At least 33 states require the physician to make a conscious decision and handwrite "no substitution", "dispense as written" or a similar statement on the pad if only a brand drug can be prescribed. Other states may have a check-off box or require the doctor to sign on a different line if they want the brand product dispensed and not a generic.

Encouraging states to simply redesign the prescription pad form could provide tremendous savings to public and private healthcare providers and consumers.

For example, before 2001 the State of Texas had a two-line prescription pad where the physician could sign the "brand only" line and override the substitution of a generic for the brand. In 2001, Texas implemented a new pad that required a physician to handwrite "Brand medically necessary" in order to prohibit generic substitution. According to an analysis by the University of Texas, this simple change resulted in estimated savings of $223 million.[3] If states were to adopt this type of approach, which makes the dispensing of an expensive brand drug a proactive choice by the physician, states would unlock a vast, untapped opportunity for savings.

We also believe that there are several additional ways to increase usage of generic drugs, by strengthening the substitution process and prescribing practices in favor of generic medicines where they are available.

Next, we believe that the issues of requiring the substitution of generics offer an untapped opportunity for savings. GPhA urges that mandatory generic substitution policies be implemented where they do not currently exist, and strengthened in states where loopholes may lower overall substitution. As an example of savings, legislation expected to be approved by the Tennessee Legislature that requires substitution of generic drugs for more expensive brand drugs has been projected by state officials to save $32 million for that Medicaid

[3] May 2001, Center for Pharmacoeconomic Studies, University of Texas at Austin

program - $11.5 million in state funds and almost $21 million in federal funds.

While the federal government may not want to specifically mandate this at the state level, CMS could certainly assist in making a compelling argument for states that do not have mandatory substitution. While CMS has recently announced its support for mandatory generic substitution policies, and most private entities already have embraced this policy, more can be done to encourage adoption by the public sectors.

GPhA would propose policies be implemented to ensure that that the substitution of generic medicines, when available, cannot be overridden without a valid medical reason.

For example, in Massachusetts, Medicaid officials took a series of steps over the past three years that they estimate shaved $150 million off the annual tab for drugs. A large part of the savings came from a change in a policy within their mandatory generic substitution program related to "Dispense as Written."

Massachusetts doctors were routinely asking for brand name drugs by writing "Dispense as Written," and Medicaid was paying $10 million to $11 million a month for brand-name drugs that had generic equivalents. After reviewing the situation, a tougher policy was put into place that requires the doctor to explain why, in writing, and get permission from the Medicaid program in order to force dispensing of a brand drug instead of its equivalent lower-cost generic. Once the new policy went into effect, spending on brand-name drugs with generic equivalents dropped dramatically to $200,000 to $300,000 a month.[4]

Another issue closely related to mandatory substitution and physician-prescribing practices involves a new version of the old argument that generic drugs are not the same as brands. This argument is appearing in the form of "carve-outs" for mental health, epileptic, diabetic, arthritis, cancer and many other drug products.

[4] Tough Medicine is Paying of For State; Boston Globe; February 17, 2004

Some states have instituted practices, supported by brand drug special interests that make it extremely easy for physicians to bypass generic drug substitution laws for mental health drugs. The rationale for carve-out provisions is based on the erroneous assumption that the use of generic drugs will undermine treatment outcomes of patients with mental illness. There is no scientific or medical basis for this assertion and it is inconsistent with FDA's determination of therapeutic equivalence.

In the mental health category alone, there are currently more than 60 major mental health drugs on the market including anti-depressants, anti-psychotics, anti-anxiety, and stimulants. Fifteen of the most prescribed mental health drugs accounted for more than $18 billion in brand name drug sales in 2001. Sales of anti-psychotics totaled $6.5 billion in 2003.

Simply stated, the "carve-out" policy is contrary to FDA's pronouncement of therapeutic equivalence, and increases state Medicaid program costs by millions of dollars without any credible, independent evidence-based studies that indicate that using a brand drug will result in a different outcome than using a generic.

To understand the cost of "carve-outs" one needs only to look to the State of Florida. Two years after the state implemented a preferred drug list with a carve-out for mental health drugs, an analysis by state officials showed that the elimination of the carve-out could provide substantial savings. And, less than two weeks ago, Florida followed through by passing legislation to eliminate carve-outs "aimed at saving nearly $300 million a year."[5]

Other states that have rejected carve-outs have achieved substantial savings without any impact on health outcomes. One year after the state of Kentucky changed its policy to treat an anti-psychotic drug like all other medications for the purpose of substitution, "mental health advocates said they could trace no ill effects to the decision."[6]

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[5] Advocates Also Point Out Concerns of Public Safety; The Tampa Tribune (May 13, 2005). The law is due to go into effect, July 1st if signed by the Governor.

[6] States Try to Limit Drugs in Medicaid but Makers Resist; New York Times; December 18, 2003.

GPhA strongly encourages the modernization and strengthening of the process by which substitution of a generic for a more expensive brand product is encouraged.

There are also several additional issues related to pricing and incentives that GPhA believes can help dramatically increase generic utilization rates. These involve implementing aggressive maximum allowable cost -- or MAC -- formulations, and providing an incentive for pharmacists to dispense generics.

States have the flexibility to establish their own payment ceilings for multiple source drugs, so long as it does not exceed the federal payment ceiling for drugs. Slightly over half the states take advantage of this cost containment tool, which enables them to limit their liability with regards to drug pricing.

Many states have implemented MACs, or maximum allowable cost formulations, for a limited number of drugs. And, while establishing aggressive MACs is certainly a worthy objective, it is the rigorous application of MACs to both brands and generics that can yield substantial state savings. This is a common practice among private health insurers that has resulted in significant savings for them.

Another opportunity for increasing generic utilization involves incentive fees for pharmacists. Drug specific payment ceilings calculated at the Centers for Medicaid and Medicare Services allow for payment to pharmacists of a “reasonable” dispensing fee established by the state Medicaid agency.

CMS regulations do not define “reasonable” and there is great variation among states in the amount of the dispensing fee and the manner in which it is calculated.[7] Lots of states offer no differential at all between the dispensing fee paid for brand-name prescription drugs and generic drugs. Offering a higher dispensing fee for generic drugs than brand drugs would encourages greater dispensing of generic drugs at the pharmacy, thus saving scarce Medicaid dollars.

[7] Ibid

Finally, an area of virtually untapped opportunity for increasing generic utilization involves the investment in consumer education programs that address misinformation campaigns by brand companies as well as misperceptions about the sameness and effectiveness of generics. An aggressive effort to educate providers and patients can result in substantial savings.

For example, AARP and Consumers Union have separately produced extraordinarily useful and empowering information to consumers to help them make the right decisions about choosing affordable medications. There are other examples as well. The *Generics First* program initiated by Medco Health Services demonstrates the impact that a generics education program can have. In 2002, Medco sent pharmacists to hold face-to-face clinical discussions with 1,700 physicians in 10 states. In addition to the meetings, the pharmacists left patient education materials and generic samples that physicians could provide to patients. The effort focused on educating the physicians on the availability, clinical benefits and economic value of generics and encouraged their use as a first line treatment.[8]

In addition, Express Scripts has implemented a program called "GenericsWork" that encourages physicians to prescribe, and patients to ask for low-cost generics. It is supported by a communication and education strategy targeted to both audiences. Express Scripts projects savings of $25 million over 3 years per 100,000 lives.

According to published reports, at least six (6) states have experimented with similar "counter-detailing" efforts. The Wall Street Journal reported that in October 2000, a Florida "counter-detailer" visited 88 physicians who tended to prescribe brand-name anti-inflammatory drugs. An analysis of those physicians prescribing habits three months later showed a change in prescribing that was expected to save Florida $196,000 a year.[9]

West Virginia launched a pilot "counter-detailing" program in 2002. The head of West Virginia's Public Employee Insurance Agency

[8] The Bergen County Record newspaper, November 5, 2002
[9] The Wall Street Journal, August 22, 2001

predicted at the outset that a 2 percent increase in generic utilization (from 43 percent to 45 percent) would save his state $1 million.[10]

GPhA has developed a consumer educational campaign designed to maximize awareness of generics. It focuses on the core message that generics are the same medicine, provide the same results, but at lower cost than brand name drugs. This educational program can be made available and distributed directly, or indirectly, and customized to suit any health care provider's needs. For example, a state could partner with GPhA or merely use the materials as they have been created to support generic product use and patient acceptance within their program - without the cost of developing such a campaign on their own.

GPhA stands ready to assist in implementing such educational programs in both the federal and state levels, as well as with employers, providers, insurers and physicians and pharmacists.

Another tremendous opportunity of untapped savings is in the area of biopharmaceuticals. Biologics are growing at almost twice the rate of total pharmaceuticals. There are more than 600 biotech drugs currently in phase II and III clinical trials. And marketed biologics are approximately $30 billion in U.S. Sales, 12 % of total pharmaceuticals, and growing about 20% annually. They could reach $60 billion in sales by 2010.

Acting Commissioner Dr. Crawford addressed the issue of biogenerics. Dr. Crawford stated that "[w]e now have the science to fashion a generics biologics program," and the agency has "to put a system in place to deal with it." GPhA couldn't agree more. The opportunity of additional savings is only a few steps away. We urge Congress to demand that FDA: (1) issue guidance documents to provide further advice to industry participants; and (2) approve generic applications that have scientific sign off. And finally, we urge Congress to encourage FDA to immediately establish a clear, definitive flexible pathway for generic biopharmaceuticals.

[10] The Washington Post, August 5, 2002

II. PREVENTING INITIATIVES THAT WOULD ERECT NEW BARRIERS TO GENERIC COMPETITION AND THUS INCREASE OVERALL COST

Ensuring that federal and international legislation as well as trade agreements do not disrupt the level playing field is necessary for the continued, timely introduction of affordable life-saving generic drugs.

These threats to savings are contained in such initiatives as attempts to use bioterrorism preparedness as a vehicle for brand product monopoly extensions; and efforts to utilize international trade agreements to restrict the development and timely approval of generics in America

For the past year, Congress has been exploring ways to expand and improve BioShield I. Senators Joseph Lieberman, Orrin Hatch and Sam Brownback introduced the Project BioShield II Act of 2005 to further improve America's security. While this legislation includes several promising incentives, it also includes provisions that would dramatically increase health care costs for consumers and the federal government and deliver windfall profits to brand pharmaceutical companies.

While GPhA supports efforts to encourage the production of countermeasures, some aspects of this legislation threaten the economic viability of our health care system. Outrageous measures to extend brand monopolies like 'wild cards' and overly generous patent extensions will delay consumers' access to affordable medicines.

For nearly 20 years, such special interest measures have been soundly rejected by Congress as catering to special interests at the public's expense. Yet, they have now resurfaced in legislation intended to strengthen America's security.

The bill contains promising incentives, such as needed product liability protections, expanded tax incentives, and fast track FDA review of drug applications, which GPhA supports. But as the legislation currently stands, it rewards *de minimis* product modifications of already approved products and discourages “true”

innovation. Simply put, it allows brand pharma to play off Americans' fears to extend their product monopolies and keep affordable medicines off the market. Accordingly, this legislation is little more than a blank check to the brand pharmaceutical industry.

GPhA remains opposed to:

- The overly broad definition of a countermeasure, which could be extended to already approved products. Because the legislation fails to limit the term to novel medicines – ones that are clinically superior and fill a security priority void -- patent extensions could be applied to a wide range of already approved drugs.

- Extending data exclusivity up to 10 years.

- Unlimited and uncapped patent extensions on any countermeasure product. Under this bill, multiple patents claiming the brand product could be extended.

- "Wild card" provisions that could be applied to any product in a company's portfolio, thus providing a windfall to brand pharmaceutical companies for products wholly unrelated to bioterrorism.

Rather than providing the brand industry with enormous windfalls, GPhA urges Congress to strengthen BioShield by adding incentives for “true” research priorities and incentives that don’t jeopardize the nation’s healthcare system.

Another threat to U.S. generic savings involves attempts to use international free trade agreements to limit the timely introduction of generics in the United States.

GPhA remains active on the international level, to ensure that harmonization efforts and treaties do not raise new barriers to the introduction of affordable medicines in the U.S., or make it difficult for generic companies to compete in the international arena.

Specifically, GPhA has serious concerns about a number of provisions contained in Free Trade Agreements (FTAs) that the United States has recently negotiated with various trading partners, including Australia, Bahrain, Chile, Morocco and Singapore, and potentially may be negotiated with Andean, SACU, ASEAN and other countries.

Some FTA provisions regarding intellectual property and other measures involving pharmaceuticals appear to contradict, both explicitly and in spirit, commitments made by the United States in the World Trade Organization and several appear inconsistent with U.S. law. GPhA is concerned that such measures could block generic drug exports abroad, substantially delay the timely access of affordable pharmaceuticals in those territories, and create the means to delay generic competition here at home, such as through international harmonization measures.

It is GPhA's position that no Free Trade Agreement should be used as a means to facilitate the brand industry's strategic global objectives of unfairly extending drug market protections and destroying the U.S. balance between pharmaceutical innovation and access.

GPhA will continue to monitor these issues, while focusing efforts on those initiatives that will help boost generic utilization and lower costs to the federal and state governments, to employers, insurers and all consumers.

In summary, it is clear that generic pharmaceuticals already save tens of billions of dollars a year in prescription drug costs. It is also clear, that with substitution at approximately 53 percent, there is still much room to grow America's utilization of generic drugs.

Ensuring the long-term growth in generic drug savings will result from Congress requiring FDA accountability and providing OGD with the resources necessary to free the logjam of new generic product approvals, by increasing the appropriations necessary to adequately fund the Office of Generic Drugs.

Additional increases in drug savings will come from changes to prescribing practices. Some of this growth can be accomplished by tightening existing substitution mechanisms. Additional growth can be accomplished by providing incentives for the increased use of generics. Some of this growth can come from educating consumers about the safety and sameness of generic medicines.

And finally, ensuring affordable generic pharmaceuticals for American consumers in the future will require that we remain vigilant to those special interests seeking, on a national or international level, to erect barriers to generic competition by unfairly extending market protections under the guise of bioterrorism preparedness, or by using international treaties to delay competition from America's generic pharmaceutical industry in the name of international harmonization.

America's generic industry is working right now to lower prescription drug costs. Prescriptions are being filled right now, one out of every two, with lower cost generics. But we can, and should do better, so we can ensure that health care and prescription drugs remains affordable for all consumers.

Thank you.